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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,761	05/14/2001	Moon Hae Sunwoo	X-9338	6883

7590

03/14/2003

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/853,761

Applicant(s)

SUNWOO ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002 (paper no.5).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Amendment filed 12/17/02 and the IDS filed 12/26/02.

The 35 U.S.C. 112, second paragraph rejections have been withdrawn.

Claims 1-37 are pending. Claims 1-4, 7, 15-17, 20, 27, 32, 33, 35 and 36 have been amended. Claims 1-37 remain rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4 are rejected under the judicially created doctrine of double patenting over claims 1 and 10 of U. S. Patent No. 6, 326,018 B1 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

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The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant claim 1 of 09/853,761 application is the species in relation to the generic claim 1 of US Pat. No. 6, 326, 018 B1. Claim 1 of Pat. No. 6, 326,018 B1 is broader in scope than instant claim 1 of 09/853,761 application, which is narrower in scope since the generic claim does not recite a thickness of the bone sheet and instant claim 1 recites a specified thickness of 2.0mm to about 8.0mm.

Instant claim 1 of 09/853,761 application is generic in relation to the species of claim 10 of US Pat. No. 6, 326,018 B1. Instant claim 1 comprises cortical and cancellous layers, whereas claim 10 recites a corticocancellous bone powder. Furthermore, the species embraced in US Pat. No. 6,326,018 B1 is embodied in generic claim 1 of 09/853,761.

Instant claim 4 of 09/853,761 application is the species in relation to generic claim 1 of US Pat. No. 6, 326,018 B1. Generic claim 1 comprises hyaluronic acid whereas instant claim 4 also comprises hyaluronic acid. The instantly claimed species embraced in claim 4 of 09/853,761 is embodied in generic claim 1 of US Pat. No. 6, 326,018 B1.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-9, 11-14, 27-31, 34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce *et al.* (US Pat. No. 5, 899,939).

Boyce teaches a flexible bone sheet for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal systems comprising a unitary structure of two or more layers: a demineralized cortical layer and another layer of a different material, wherein the thickness of the layers range from about 0.5 mm to 20 mm (see reference column 1, lines 1-17); (column 3, lines 11-40).

Boyce *et al.* while teaching a demineralized cortical bone sheet do not explicitly teach the specified residual calcium weight percentages. It would have been obvious to one of ordinary skill in the pharmaceutical art to determine suitable residual calcium percentages through routine or manipulative experimentation.

Boyce *et al.* while teaching a bone sheet are lacking in that they do not explicitly teach a sterile bone sheet. It is deemed obvious to one of ordinary skill in the art to apply only sterile materials when used for implantation into human or animal skeletal systems.

Claims 4, 10, 15-26, 32, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce *et al.* ('939) in view of Boyce *et al.* (US Pat. No. 6, 294,187 B1), hereinafter ('187).

Boyce ('939), as discussed above, teaches a flexible bone sheet for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal systems comprising a unitary structure of two or more layers: a demineralized cortical layer and another layer of a different material, wherein the thickness of the layers range from about 0.5 mm to 20 mm (see reference column 1, lines 1-17); (column 3, lines 11-40).

Boyce do not explicitly teach hyaluronic acid in the bone composition.

Boyce ('187) teaches an osteoimplant bone composition for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal systems comprising demineralized cortical and cancellous portions, wherein mucopolysaccharides can be added to the bone composition (see reference column 9, lines 6-15).

Therefore, it would have been obvious to one of ordinary skill in the art to add a mucopolysaccharide in a bone composition, which is a suitable biostatic/biocidal agent used to prevent contamination, with the expected result of obtaining a bone particle composition that contains a minimal amount of bacteria and aids in bone formation.

Boyce ('187) do not teach the instantly claimed molecular weights of hyaluronic acid. It is deemed obvious to one of ordinary skill in the art that suitable molecular weights could be obtained through routine or manipulative experimentation.

Response to Arguments

The applicants arguments filed 12/17/02, have been fully considered, but are not found to be persuasive.

Firstly, the applicant argued regarding the 35 U.S.C. 103(a) rejection of Boyce et al. (US 5,899,939), in that, "The Boyce reference is a bone derived implant of a composite structure which is made up of at least two superimposed layers of fully mineralized or demineralized or partially mineralized cortical bone material adhesively secured or fastened to each other to form a single rigid structure which was then cut into shaped implants. It is not made from a single piece of formed bone."

This argument has been fully considered, but was not found to be persuasive. Boyce teaches a flexible bone sheet for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal systems comprising a unitary structure of two or more layers. Although Boyce uses two layers for the bone implant, he does teach an end product that is unitary in form and structure. Furthermore, the examiner points out that the instant claims are "comprising" claims and as such, the comprising claim language does not exclude, but rather, permits the use of additional ingredients in the bone implant composition.

Secondly, the applicant argued, "There is no discussion of the amount of demineralization and that Boyce does not teach residual calcium left after demineralization because the bone is fully demineralized to achieve osteoinductiveness."

This argument has been fully considered, but was not found to be persuasive. Boyce teaches a bone implant that has been partially and fully demineralized. Boyce does not recite the instant amounts of demineralization or calcium residual percentages. One of ordinary skill in this art would determine suitable percentages or ranges, since such amounts are viewed as being variable parameters. In addition, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

The applicant also argued regarding the secondary reference of Boyce et al. (US 6,294,187). The applicant argued, "Boyce simply teaches an osteoimplant bone composition formed of bone particles and there is no teaching using a sheet of cancellous bone as part of a bone sheet in a continuous integral sheet of bone used for surgical repair."

This argument has been fully considered, but was not found to be persuasive. Boyce teaches an osteoimplant bone composition for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal systems comprising demineralized cortical and cancellous portions. The osteoimplant can be

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formed into various shapes and sizes, such as wedges, plates, cylinders, etc. Additionally, the examiner points out that the Boyce ('187) reference was relied upon for the teaching of mucopolysaccharides in the bone implant formulation, as Boyce ('939) initially recited the teaching of a unitary structured bone implant comprising layers. Furthermore, the prior art teaches a similar bone implant composition for the repair, replacement and/or augmentation of various portions of animal or human skeletal systems, as similarly desired by the applicant.

Lastly, the applicant argued, "The examiner's Double Patenting rejection is without merit as the '018 patent is directed toward a totally different invention."

This argument has been fully considered, but was not found to be persuasive. The examiner has maintained the Double Patenting rejection since the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

March 1, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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